EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE:	)	
	)	
E.R.G., a minor, by CHRISTINA RAQUEL, individually as parent and next friend of E.R.G.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Case No. 15-CV-702-NJR-SCW**
	)	
ABBOTT LABORATORIES, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM AND ORDER

ROSENSTENGEL, District Judge:

Pending before the Court are eleven motions *in limine* filed by Plaintiffs and seventeen motions *in limine* filed by Defendant.

A district court's authority to rule on motions *in limine* is derived from its inherent authority to control the course of trials. *See Luce v. United States*, 469 U.S. 38, 41, n. 4 (1984). "[A] motion *in limine* should be granted only if the evidence sought to be excluded is clearly inadmissible for any purpose." *Noble v. Sheahan*, 116 F. Supp. 2d 966, 969 (N.D. Ill. 2000). Motions *in limine* are intended "to avoid the delay and occasional prejudice caused by objections and offers of proof at trial." *Wilson v. Williams,* 182 F.3d 562, 566 (7th Cir. 1999). Such motions permit the district court to eliminate evidence "that clearly ought not be presented to the jury," because it is inadmissible for any purpose. *Jonasson v. Lutheran Child and Family Services,* 115 F.3d 436, 440 (7th Cir. 1997).

"[T]he party moving to exclude evidence *in limine* has the burden of establishing that the evidence is not admissible for any purpose." *Euroholdings Capital & Inv. Corp. v. Harris Trust & Sav. Bank*, 602 F. Supp. 2d 928, 934 (N.D. Ill. 2009).

Motion *in limine* rulings "are made before the district court has had a chance to hear all of the evidence or see the trial develop." *Currie v. Cundiff,* No. 09-cv-866-MJR, 2012 WL 2254356, at *1 (S.D. Ill. June 15, 2012). As such, these rulings are preliminary and may be revisited based on the court's exposure to the evidence at trial. *Id*.; *United States v. Connelly*, 874 F.2d 412, 416 (7th Cir. 1989).

Some evidentiary submissions cannot be evaluated accurately or sufficiently prior to trial. *Jonasson*, 115 F.3d at 440. "In these instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate its impact on the jury." *Id*. Further, the denial of a motion *in limine* does not preclude a party from objecting to any evidence at trial or from requesting a limiting instruction. *Team Play, Inc. v. Boyer*, No. 03-C-7240, 2005 WL 3320746, at *1 (N.D. Ill. Dec. 5, 2005).

The motions have been thoroughly briefed, and the Court heard from the parties concerning particular questions on certain motions at the final pretrial conference on May 5, 2017. For the reasons set forth below, the Court rules as follows.

A. PLAINTIFFS' MOTIONS *IN LIMINE*

1. Plaintiffs' Motion *in limine* Nos. 1 and 5—To exclude evidence, argument, or discussions regarding any collateral support Plaintiff E.R.G. received or will receive from sources wholly independent of the Defendant (Doc. 195).

GRANTED. The collateral source doctrine states that "if an injured party receives some compensation for his injuries from a source wholly independent of the tortfeasor, such payment should not be deducted from the damages which the plaintiff

would otherwise collect from the tortfeasor." *Hrnjak v. Graymar, Inc.*, 4 Cal. 3d 725, 729, 484 P.2d 599, 602 (1971). Moreover, gratuitous care is not guaranteed or even legally required after the minor plaintiff turns eighteen.

2. **Plaintiffs' Motion *in limine* No. 2—To exclude argument that Defendant was prohibited from changing the Depakote label without prior approval from the FDA (Doc. 195).**

GRANTED in part and DENIED in part. Any evidence or testimony that Abbott should have implemented a developmental delay warning prior to E.R.G.'s *in utero* exposure to Depakote is not admissible at trial. *See* (Case No. 14-CV-847, Doc. 285, pp. 4-10) (containing a detailed analysis on the preemption of label changes related to development delay). As to other evidence that Defendant could have changed the Depakote label via the Change Being Effected process, Defendant will be allowed to explain that the FDA maintains the authority to accept, reject, or request modification of those changes.

3. **Plaintiffs' Motion *in limine* No. 3—To exclude statements or arguments that mischaracterize evidence or misstate facts central to the present litigation (Doc. 195).**

DENIED. All counsel are bound by the ethical rules of professional conduct, the local rules, and the Federal Rules of Civil Procedure. This issue cannot be properly addressed outside the context of the evidence introduced and the specific objection raised at trial. Accordingly, the Court will take up objections to alleged mischaracterizations of evidence or misstatements of fact on a case-by-case basis during the course of trial.

4. **Plaintiffs' Motion *in limine* No. 4—To exclude any argument or suggestion that implies that it is the FDA's responsibility to conduct post-market studies of medications or that the Depakote label is what the FDA wanted (Doc. 195).**

GRANTED in part and DENIED in part. Statements implying that the FDA had a legal duty to conduct post-market studies of medication will not be allowed. However, whether Defendant followed existing labeling regulations to produce a label "the FDA wanted" will be subject to expert testimony on direct and cross-examination.

6. **Plaintiffs' Motion *in limine* No. 6—To exclude evidence, argument, and testimony regarding any alleged negligence or fault of Christina Raquel or of Christina Raquel's pre-pregnancy knowledge of risks (Doc. 196).**

GRANTED in part and DENIED in part. At the final pretrial conference, Defendant agreed to not argue or introduce evidence that Christina Raquel was negligent or at fault for the alleged injuries to E.R.G. (Doc. 262, pp. 27-31). Defendant does, however, seek to introduce evidence of what Christina Raquel was told regarding the risk of birth defects and what her response was to that knowledge. Plaintiffs assert that this is irrelevant evidence because the dispositive question concerns whether or not her doctors would have prescribed Depakote given the proposed stronger warnings. (Doc. 262, p. 26). While this may be partially true, the prescription decision is not made in a vacuum. If evidence in the case indicates that the prescribing decision was based in part on the conversations, understanding, and preferences of the patient, then the patient's knowledge of the risks and responses to that information are directly connected to the ultimate issue.

For example, in a recent key prescriber status report, Plaintiffs asked the doctor whether or not he would have shared the alleged increased risk with the patient in making the prescribing decision. Plaintiffs then asked the doctor, if the patient did not

want to take Depakote in light of the increased risk, would he have still prescribed it. The doctor stated he would not have prescribed Depakote under those circumstances. *See* (Case No. 12-CV-52, Doc. 947, pp. 2-3). Such patient involvement in the prescription decision makes the patient's knowledge and responses to the risks and benefits clearly probative to the ultimate question. But this ruling should not be read as a campaign *carte blanche* to "blame the mother." Abbott is cautioned that its questioning on this topic will be limited.

7. Plaintiffs' Motion *in limine* No. 7; 8; 9—To exclude certain details of Christina Raquel's personal history (Doc. 201)(unsealed)(Doc. 202)(sealed).

GRANTED in part and DENIED in part. Plaintiffs seek to exclude details of Christians Raquel's personal history including evidence of her experience with domestic abuse or violence, her suicidal ideations or attempts, or her family history of mental illness. Abbott has indicated that "[a]t present, Abbott does not intend to present evidence of any alleged neglect or possible abuse that Ms. Raquel experienced as a minor." (Doc. 249, p. 3).

At the final pretrial conference, Plaintiffs asserted that beyond this one concession, there is no need to introduce any of this information as "it is undisputed that Ms. Raquel suffers from bipolar disorder." (Doc. 262, at pp. 33-32). Plaintiffs have clearly indicated, however, that they intend to challenge the appropriateness of the prescription decisions for Ms. Raquel. (Doc. 262, at p. 35) ("Ms. Raquel was prescribed [Depakote] for an off-label purpose…."); *see also* (Doc. 253). It is also clear that Plaintiffs seek to argue that Ms. Raquel did not need to be on Depakote at all, as evidenced by her post-conception treatment regime. (Doc. 262, at pp. 63-65). The unfortunate nature of Ms.

Raquel's disorder necessarily means that the sensitive details of her symptoms, as they are manifest (assuming a cognizant expert adequately connects the conduct with her disorder), will be allowed in at trial. Abbott will only be given a small amount of latitude on these subjects and therefore should use great caution in developing questions.

10. Plaintiffs' Motion *in limine* No. 10—To exclude evidence, argument, and testimony regarding any alleged negligence or fault of Christina Raquel's prescribing physicians (Doc. 198)(sealed); (Doc. 197)(unsealed).

GRANTED. Plaintiffs seek to exclude any evidence, inference, argument, or testimony that Ms. Raquel's prescribing physicians were somehow negligent or at fault with respect to what they did or knew about birth defects associated with Depakote use. (Doc. 197, p. 1). At the final pretrial conference, Defendant articulated that it does not contest the motion. (Doc. 262, at pp. 33-34) ("[O]ur case does not include anything that suggests that the physicians—the four physicians who saw her at El Hogar during this time period and had any interaction with her on her Depakote prescription were at fault in any way.").

11. Plaintiffs' Motion *in limine* No. 11—To admit evidence, testimony, and argument regarding the May 2012 plea agreement, civil settlement, and corporate integrity statement in this particular case (Doc. 205).

GRANTED in part and DENIED in part. See the Court's Order regarding Abbott's motion *in limine* No. 17.

B. DEFENDANT'S MOTIONS *IN LIMINE*

1. Defendant's Motion *in limine* No. 1—To exclude references to post-conception labeling and regulatory communications (Doc. 199).

GRANTED. Defendant seeks to exclude evidence of post-conception labeling and regulatory communications. Every Court to review this issue has excluded the post-conception labels and communications with the FDA under Rule 407 and/or Rule 403. Plaintiffs do not contest Defendant's motion, rather they seek a reciprocal prohibition on "any pre-conception regulatory communications between Abbott and the FDA regarding these prospective label changes that were not approved and effective at the time of Plaintiffs' conception." During the final pretrial status conference, Defendant agreed to the exclusion of the above quoted language. (Doc. 262, p. 57-58).

2. Defendant's Motion *in limine* No. 2—To exclude references to the December 3, 2009 FDA Alert (Doc. 208).

GRANTED. Defendant seeks to exclude an alert posted by the FDA on its website "reminding health care professionals about the increased risk of [birth defects] in babies exposed to [Depakote] during pregnancy." (Doc. 208-1, p. 1). Two facts are dispositive in excluding this document under Rule 403. First, Plaintiff E.R.G. was conceived three years *before* the alert was published. Second, the two page alert is not a "study" or other academic paper that provides further clarification as to Depakote's known teratogenicity back the in pre-2006 timeframe. Instead, the document simply draws attention to existing studies—generated outside the FDA—in an effort to "remind" healthcare providers of the serious risks of birth defects. In short, any probative value to this case is dramatically outweighed by the risk of prejudice and confusion. Again, however, this Order should not be read as an exclusion of the underlying studies that existed before

E.R.G.'s conception.

3. Defendant's Motion *in limine* No. 3—To preclude admission of a document titled "neurology consultant meeting" and other suggestions that Depakote should have been contraindicated for the treatment of epilepsy in women of childbearing years (Doc. 215).

GRANTED. Defendant seeks to exclude (1) a specific document produced during discovery and (2) any suggestion that Depakote should be contraindicated for women of child bearing years. The first sub-issue concerns a document known as "Carbone 921." The document was produced by Abbott during the discovery process when it "hit" during an electronic search of Abbott's records based on agreed upon search terms. Carbone 921 is a typed document concerning a meeting in Chicago, Illinois, in 2001. Plaintiffs seek to introduce the document due to the following language:

> 4) Discuss develop a flowchart for the treatment of adult epilepsies and co-morbid conditions (eg, behavioral disorders).
>
> - Not use Depakote in female of child bearing years due to teratogenic potential. Many not aware of the actual risk. Dr. Hughes quoted 1-2% of neural tube defects, just not sure with new AEDs.

(Doc. 215-1, p. 3). Plaintiffs assert that the document is in essence a smoking gun showing that Abbott knew back in 2001 that Depakote should not be used in the female population of childbearing potential. Plaintiffs' assertion is highly speculative and requires an untenable number of assumptions to reach such a conclusion. First, no one has been able to identify the author of the document, nor is there any evidence as to how the document came to be in the possession of an Abbott custodian. Beyond the foundational and hearsay problems presented by the untethered document, the fragmented short-hand sentence is inherently unclear in its true meaning. Showing Carbone 921 to the jury absent evidence of its author's identity and intent, or sufficient

details concerning the June 2001 Chicago meeting, is to invite impermissible speculation.

The second sub-issue in Defendant's motion *in limine* ties directly into Carbone 921 and Plaintiffs' assertion that Abbott knew Depakote "should not be administered to women of childbearing years." Defendant argues that no expert has ever disclosed such a sweeping opinion that Depakote is never appropriate for woman of child bearing potential. In response, Plaintiffs assert that their labeling and regulatory expert, Dr. Kessler, clearly states: "Abbott's Depakote labeling should have stated that valproate should not be used to treat women of childbearing age with the forms of epilepsy and phases of bipolar disorder for which it has been approved unless all other available medications have failed to control their symptoms or are otherwise unacceptable." (Doc. 247, pp. 2-3) (emphasis omitted). Dr. Kessler's use of the word "unless" makes Defendant's very point.

Should Plaintiffs seek to introduce expert testimony that Depakote should *never* be prescribed to woman of child bearing potential *under any circumstance*, counsel will need to bring to the Court's attention a previously disclosed expert report containing such a sweeping, blunt assertion.

4. **Defendant's Motion *in limine* No. 4—To exclude references to post-conception codes of business conduct, ethical guidelines, or similar documents promulgated by Abbott, FDA, PhRMA, or any other entity (Doc. 213).**

RESERVE RULING. The Court will instruct the jury on the law and what Abbott's duty was to Plaintiffs. At the previous *Kaleta* trial, the parties agreed that they would bring any issues relating to this motion *in limine* to the Court's attention before evidence of this type is introduced at trial. The parties are instructed to follow the same

course of action as previously utilized in *Kaleta*. To the extent evidence of this nature is contained in the video depositions, the parties shall raise objections with the Special Master.

5. Defendant's Motion *in limine* No. 5—To exclude evidence and testimony about legal standards, duties, and obligations (Doc. 218).

RESERVE RULING. This motion is closely related to Abbott's motion *in limine* No. 4, discussed above. Again, the Court will instruct the jury on the applicable law regarding Abbott's duty. The admissibility of this evidence depends on the context and nature of the questions posed. Plaintiffs accurately pointed out at the final pretrial conference that there is an important distinction between commenting on the FDA regulatory scheme as opposed to commenting on the tort duties Defendant owed to E.R.G. The Court intends to address these concerns at trial where the nuance of the questions and potential answers can be assessed by the Court. The Court also intends to offer a more thorough evaluation of the issue as it relates to Dr. Kessler in the Order addressing Defendant's pending *Daubert* motion.

6. Defendant's Motion *in limine* No. 6—To limit references to comparative teratogenicity data (Doc. 211).

DENIED. The birth defect warning for Depakote is identical regardless of whether it is prescribed for bipolar or epilepsy; additionally, the 2006 label included a sentence likening Depakote to other antiepileptic drugs. The combination of these two facts makes comparative teratogenicity data of other available antiepileptic drugs and psychiatric drugs relevant to this case. Plaintiffs will be allowed to introduce evidence concerning the comparative teratogenicity of all antiepileptic drugs or psychiatric drugs

available before the conception of E.R.G. If Abbott believes alternative drugs were not appropriate for Ms. Raquel, then they are free to evaluate such assertions on cross-examination. This Order should not be read as allowing references to other drugs unrelated to the treatment of bipolar or epilepsy, *i.e.* reference to Thalidomide or Accutane.

7. Defendant's Motion *in limine* No. 7—To exclude references to promotional, marketing, or sales activities (Doc. 216).

DENIED in part and RESERVED RULING in part.

Abbott seeks to preclude Plaintiffs from presenting testimony, evidence, argument, and other references to promotional, marketing, or sales activities and materials. In the alternative, they seek to exclude three specific categories of marketing material. (Doc. 216, at pp. 1-2). The Court denied a similar Abbott motion *in limine* in *Kaleta* based on the following rationale:

> Even without testimony that these materials affected the decisions of Mrs. Kaleta's physicians (and it is not entirely clear at this point that is the case), this evidence is, on the issue of what Abbott knew and when it knew about the scope of Depakote's birth defect risks and its proper use in women of childbearing years. This evidence may also be relevant to the content of the 1999 label if, as Plaintiffs suggest, they can show that Abbott's marketing strategy influenced its label. As Judge Herndon found in the Yaz cases, "evidence about sales goals is certainly relevant particularly when it may impact decision making regarding labeling." *In re: Yaz,* at *10; *see also In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 369 F.3d 293, 314 (3d Cir. 2004) ("[E]xcessive concern with the image and marketing of the diet drugs at the expense of making efforts toward determining whether they were safe could be probative as to whether [the manufacturer] breached a duty of care towards the plaintiffs.").

(Case No. 14-CV-847, Doc. 285, at pp. 17-18). Defendant has not provided any new information or arguments that counter the probative value of this evidence. Indeed, unlike in *Kaleta* where it was unclear whether marketing material reached the

prescribing physicians in question, here Plaintiffs assert that there are call sheets indicating sales representatives directly marketed to Raquel's physicians. (Doc. 262, at p. 36).

To summarize, marketing materials issued before the birth of E.R.G. are certainly relevant; a decision about post-2006 marketing materials will have to be made on a case-by-case basis, but unless they contain pre-2006 facts, it is likely that they are not relevant. The probative value of marketing materials available before E.R.G.'s birth is not outweighed by the danger of unfair prejudice, confusion, or waste of time. Additionally, because the teratogenicity warning section of the Depakote label is identical regardless of the indication, marketing material for epilepsy and migraine indications will not be excluded (subject to Plaintiffs' ability to connect the evidence to the 2006 label or Abbott's knowledge).

8. Defendant's Motion *in limine* No. 8—To exclude reference to off-label use or promotion (Doc. 217).

DENIED. Defendant seeks to exclude any reference that Christina Raquel was prescribed Depakote for an off-label purpose. Plaintiffs have indicated that Depakote was authorized only for the treatment of the acute manic phase of the bipolar disorder. At the final pretrial conference they indicated that prescribing the medication for over three weeks indicates that she was prescribed Depakote as a maintenance medicine, which they allege is an "off-label" purpose. This issue is directly related to Defendant's motion *in limine* No. 14 and No. 17. As Defendant will almost certainly argue that Christina Raquel's use of Depakote was appropriate and necessary, Plaintiffs will be allowed to ask questions and introduce evidence surrounding the prescribing decisions,

as well as introduce evidence concerning efforts by Abbott to market Depakote for off-label bipolar treatment. The evidence of Abbott's conduct concerning pushing Depakote for unapproved bipolar treatment is admissible, as Plaintiffs put it in *Kaleta*, to demonstrate that Abbott had a corporate climate where marketing and sales trumped patient safety.

9. **Defendant's Motion *in limine* No. 9—To exclude references to two draft abstracts and a draft manuscript reporting North American Antiepileptic Drug Registry data (Doc. 221).**

DENIED. Defendant seeks to exclude references to draft abstracts concerning the preliminary data from the North American Antiepileptic Drug Registry as well as any email exchanges between the authors and Abbott. The primary argument from Defendant is that there is no evidence that Ms. Raquel's doctors ever saw the material. Plaintiffs counter by arguing that this is evidence that Abbott was made aware of negative information concerning the teratogenicity of birth defects but instead of publishing the information, people at Abbott sought to suppress it. They point directly to the fact the marketing officials were included in the email exchanges used to influence the choice of language in the final reports. This information certainly is relevant to Plaintiffs' theory that marketing decisions were impacting the label. Additionally, the probative value of this information is not outweighed by the danger of unfair prejudice, confusion, or waste of time.

10. **Defendant's Motion *in limine* No. 10—To exclude duplicative testimony (Doc. 220).**

DENIED. Defendant's request is overly broad and context dependent.

11. **Defendant's Motion *in limine* No. 11—To exclude the recitation of exhibits as evidence (Doc. 219).**

DENIED. Defendant's request is overly broad and context dependent.

12. **Defendant's Motion in limine No. 12—To preclude prescribing physicians who may testify live at trial from testifying about the adequacy of Abbott's warnings and/or offering testimony beyond that provided during their depositions (Doc. 214).**

GRANTED in part and DENIED in part. All of the treating physicians for Ms. Raquel were designated during discovery as fact witnesses under Rule 26(a)(1)(A). (Doc. 243, p. 3). They were not designated as expert witnesses. Accordingly, the treating physicians will be prohibited from offering expert testimony that falls within the scope of Rule 702. For example, Plaintiffs will not be able to ask questions regarding what Abbott knew or should have known about Depakote's teratogenicity. Nor will they be allowed to offer opinions as a subtitle for an expert psychiatrist regarding Ms. Raquel's future treatment (or speculate as to the appropriate treatment for Ms. Raquel once she departed their respective practices).

Each physician will be allowed, however, to offer testimony concerning his or her observations, diagnosis, and treatment of Christina Raquel. The Court will address objections on a case-by-case basis throughout course of trial. Finally, the Court will not prophylactically limit the treating physicians to the information provided in their depositions. Any addition or change from the deposition is appropriately handled through cross-examination and impeachment.

13. **Defendant's Motion *in limine* No. 13—To exclude references to foreign product warnings (Doc. 210).**

DENIED. This motion seeks to exclude the label for Epilim, the version of

Depakote sold in the United Kingdom and elsewhere in Europe. Abbott contends that foreign product labels and the regulatory actions are irrelevant to any issue in this case because "Ms. Raquel was prescribed Depakote to treat the severe, recurrent manic symptoms caused by her bipolar disorder.... [whereas the] foreign regulators [approved Depakote] to treat epilepsy—a different disease with different alternative medications and different risk-benefit considerations." (Doc. 210, at p. 1).

The Court disagrees. This evidence is relevant on the issue of Abbott's *knowledge* during a relevant time period (before E.R.G.'s conception) about the drug it introduced into the United States market. *See In re: Yaz*, 2011 WL 6740391, at *2 ("While the regulatory actions of European Medical regulators are not binding on the FDA—a fact that should be made clear to the finders of fact in this case to avoid confusion—the full body of knowledge including the foreign regulatory process that came to bear on the drugs at issue and which were well within the notice and knowledge of [the manufacturer] is admissible as part of the fabric of how these drugs came to the United States market and whether all the information which should have been utilized in doing so was utilized."); *see also Newman ex rel. Newman v. McNeil Consumer Healthcare,* No. 10 C 1541, 2013 WL 4460011, at *13 (N.D. Ill. Mar. 29, 2013) (Denying Defendants' motion *in limine* because "[t]he probative value of . . . foreign labeling, as it relates to Defendants' knowledge of the risks and willfulness in not sharing certain of those risks on its American OTC label, is not substantially outweighed by the time, potential for cumulative evidence, or risk of confusion to the jury.").

The teratogenicity warning section in the Depakote label is identical regardless of

the indication. Clearly the teratogenicity of Depakote is independent of the indication for which it is approved. The fact that there are "alternative medications and different risk-benefit considerations" is fertile ground for cross-examination, but it is not grounds to exclude evidence of the original Epilim label.

14. Defendant's Motion *in limine* No. 14—To exclude references to Christina Raquel's post-conception lawful prescription drug use.

DENIED. Defendant seeks to exclude evidence concerning the prescription medications taken by Christina Raquel to treat her bipolar disorder following the conception of E.R.G. The Court understands that Ms. Raquel stopped taking Depakote following the conception of E.R.G. In each case tried to date where the minor child's mother took Depakote following the conception, Abbott has sought to introduce the evidence of that use at trial. Defendant claims that Plaintiffs cannot lay the proper foundation to make the post conception drug use relevant because they do not have an expert psychiatrist to talk about the appropriateness of future prescription decisions.

Plaintiffs respond by first noting "on the issue of foundation, Abbott very conveniently omits the testimony of two of the prescribers who listed a whole laundry list of available alternative medications at the time, which include medications that she has taken since the birth…." (Doc. 262, at pp. 63-64). Plaintiffs also correctly point out that "Abbott is going…. to tell this jury—through their expert… that Depakote was a necessary and essential medication for [Christina Raquel]." (Doc. 262, at p. 64).

It is clear from the arguments at the final pretrial conference and through other briefing that Abbott intends to introduce evidence that Depakote was an appropriate and necessary treatment for Ms. Raquel prior to the conception of E.R.G. What

medications she took to treat her bipolar disorder following the conception of E.R.G. is certainly relevant to the veracity of this assertion. Objections based on foundation will be addressed at trial based on the nature and circumstances of the question posed.

15. **Defendant's Motion *in limine* No. 15—To exclude references to the heeding presumption.**

GRANTED. The parties agree that California has not adopted the heading presumption; thus, there will be no reference to this legal doctrine.

16. **Defendant's Motion *in limine* No. 16—To exclude references to alleged future problems of E.R.G. not supported by expert testimony to a reasonable degree of medical certainty (Doc. 200).**

RESERVE RULING. Defendant has presented excerpts from Dr. Lott's deposition indicating that for certain future medical conditions of E.R.G. he cannot say to a reasonable degree of medial certainty whether they will occur. Plaintiffs counter by pointing to his expert report and sections of his deposition transcript claiming that these same opinions are to a reasonable degree of medical certainty. With this contradiction, the Court must reserve its ruling on the issue until after Dr. Lott has testified regarding the future prognosis of Plaintiff E.R.G.

17. **Defendant's Motion *in limine* No. 17—To exclude evidence, testimony, argument, and other references to the May 2012 plea agreement, civil settlement, and corporate integrity agreement in this case (Doc. 230).**

GRANTED in part and DENIED in part. In 2012, Abbott pleaded guilty to a misdemeanor crime and settled an entirely different suit, all related to illegal off-label marketing efforts by the company towards individuals with schizophrenia and elderly dementia.[1] In the *Kaleta* trial, a case involving an epilepsy disorder, the Court excluded

[1] Depakote has never been approved as a safe and effective treatment option for individuals with

this same evidence commenting as follows:

> The fact that Abbott pleaded guilty to a misdemeanor crime and settled an entirely different suit has no relevance in this case. Even if it had minimal probative value, any probative value is outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, undue delay, and/or wasting time. The Court doubts that this evidence would even be admissible for the purpose of impeachment (unless Abbott opens the door) or punitive damages. Counsel shall alert the Court during trial if it intends to offer this evidence or elicit testimony relating to it in any way.

(Case No. 14-CV-847, Doc. 289, p. 4). Plaintiffs seek to introduce this evidence in *Raquel* because "the cited violative conduct is related and substantively connected to how Abbott's comprehensive psychiatric marketing strategy influenced its label and impacted Abbott's decision-making regarding labeling." (Doc. 238, at p. 2).

There is no denying that Abbott engaged in a systematic effort to increase sales by attempting to expand Depakote prescriptions for other non-approved indications. It appears, however, that Plaintiffs cannot sufficiently connect these activities with the 2006 Depakote teratogenicity warning. The fatal flaw in their assertion is that the link between the off-label marketing for elderly dementia and schizophrenia is far too attenuated to the teratogenicity warnings in the 2006 label. Even if the Court were to accept that the "violative" marketing concerning these two unapproved indications influenced the teratogenicity labeling in this case, the risk of confusion and unfair prejudice outweighs the limited probative value. Every trial attorney would relish an opportunity to talk about how their opponent was found guilty and paid over a billion dollar fine in a case. The reasoning is simple; the jury would be galvanized against the "guilty" party from the onset of trial, regardless of whether or not the underlying action

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schizophrenia or elderly dementia.

was connected to the case at hand. Even attempts to explain the distinction would play into this prejudice as it would simply keep the topic fresh in the minds of the jury.

On the other hand, however, Plaintiffs will be allowed to introduce evidence regarding the off-label marketing and sales efforts by Abbott regarding the bipolar disorder. This evidence is relevant to Plaintiffs theory that the corporate culture at Abbott valued marketing and sales over patient safety. Also, unlike schizophrenia or elderly dementia, bipolar disorder will be discussed at length throughout trial, thereby limiting the risk of undue prejudice and confusion of the jury.

IT IS SO ORDERED.

DATED: May 16, 2017

NANCY J. ROSENSTENGEL
United States District Judge